



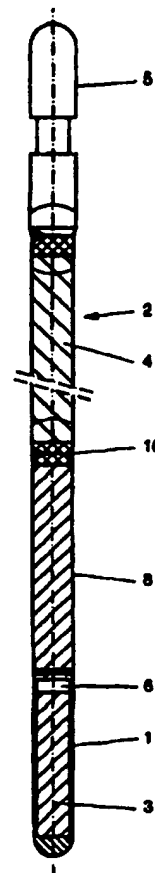
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61N 5/10	A1	(11) International Publication Number: WO 98/01184 (43) International Publication Date: 15 January 1998 (15.01.98)
(21) International Application Number: PCT/NL97/00385 (22) International Filing Date: 4 July 1997 (04.07.97) (30) Priority Data: 1003528 5 July 1996 (05.07.96) NL (71) Applicant (for all designated States except US): B.V. OPTISCHE INDUSTRIE "DE OUDE DELFT" [NL/NL]; Postbus 72, NL-2600 MD Delft (NL). (72) Inventors; and (75) Inventors/Applicants (for US only): LÖFFLER, Edgar, German [DE/DE]; Bresserbergstrasse 72, D-47533 Kleve (DE). VISSCHER, Arie, Luite [NL/NL]; W. Banninglaan 33, NL-3972 SJ Driebergen (NL). (74) Agent: VAN DER BURG, Louis; B.V. Optische Industrie "De Oude Delft", Postbus 72, NL-2600 MD Delft (NL).		(81) Designated States: CN, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>In English translation (filed in Dutch).</i>

(54) Title: COMBINATION OF A CAPSULE FOR BRACHYTHERAPY AND A GUIDEWIRE

(57) Abstract

A combination of a capsule for incorporating a radioactive source to be applied in brachytherapy and a guidewire, in which the capsule is attached to the guidewire via an adapter, and the adapter comprises a cable or thread with a flexibility greater than that of the guidewire.



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

BEST AVAILABLE COPY

- 1 -

Title: Combination of a capsule for brachytherapy
and a guidewire.

5 The invention relates to a combination of a capsule for incorporating a radioactive source to be applied in brachytherapy and a guidewire.

Such a combination is known in practice and described, for instance, in U.S. patent no. 4,861,520, which is herewith incorporated by reference.

10 For local radioactive radiation treatment of a specific internal area of the human body, such as a tumor, or a wall section of a blood vessel, it is possible, as described in U.S. patent 4,861,520, to deliver a capsule with a radioactive source, via a hollow needle, a flexible tube or a catheter or the like, to the area to be treated.
15 For this purpose, normally the so-called "after loading" technique is employed. First, the catheter, or the like, is placed in the body and then the capsule attached to the distal end of a guidewire is delivered with the help of a remotely controlled device to the treatment area.

20 The combination of the capsule and guidewire should, on the one hand, have a high degree of flexibility to be able to follow the curves of a catheter or the like, and on the other, a certain rigidity, so that the capsule can be pushed through a catheter toward its distal end with
25 the help of the guidewire. For the application in endovascular brachytherapy, a catheter normally has an inside diameter on the order of 1.5 mm or less. The length of a capsule depends on the desired strength of the radioactive source placed in the capsule, but should be on
30 the order of several times the diameter, for instance in the range of 5 to 7 mm. The capsule itself and its connection with the guidewire are not flexible, so that the front part of the combination of guidewire and capsule has a relatively low degree of flexibility. Thus there is a
35 certain probability that the capsule cannot pass the curves in a catheter with a strong curvature or only passes with difficulty.

The invention is intended to reduce the outlined problem and, in general, to make available a combination of
40 a capsule and a guidewire that can be applied in a reliable way in a large number of situations, including situations

- 2 -

in which strongly curved courses are to be passed in the catheter or the like.

For this purpose, a combination of the above-mentioned type is characterized in that the capsule is attached to the guidewire via an adapter, in which the adapter comprises a cable or a thread with a flexibility greater than the flexibility of the guidewire.

The invention will be described in more detail in the following with reference to the attached drawing of some embodiments.

Figure 1 shows a diagram of a first embodiment of a combination according to the invention; and

Figure 2 shows a diagram of a second embodiment of the combination according to the invention.

Figure 1 shows a diagram of a first embodiment of a combination of a capsule 1 for brachytherapy and a guidewire 2. The capsule comprises one or more radioactive sources, for example a small Iridium rod 3, as shown in the drawing. The guidewire 2 comprises in a known manner a thin cable 4, which at its proximal end is provided with a coupling element 5 in order to manipulate the guidewire with the capsule. Usually, the cable 4 has essentially the same diameter as the capsule 1. The cable 4 is both supple and solid, so that on the one hand, it can be used to push the capsule through a catheter or the like, and on the other is able to follow a curved path in a catheter or the like. The cable has a diameter that may not be much smaller than the inside diameter of the catheter or the like, since otherwise there is a risk that the cable will rest in a meandering way in the catheter or the like, whereby the position of the capsule with regard to the proximal end of the catheter or the like no longer is clearly defined.

In the known combinations, the capsule is attached to the distal end of the cable via a connecting piece 6, e.g., through a laser weld. As a consequence, the front end of the guidewire forms a rather rigid entity thereby restricting the ability of the capsule to follow strongly bent curves in the catheter or the like. According to the invention, the flexibility of the front end of the combination of the capsule and guidewire is therefore improved, since the capsule with its connecting piece is not directly attached to the distal end of the cable 4, but rather through a thread or cable-shaped adapter having a

BEST AVAILABLE COPY

- 3 -

higher degree of flexibility than cable 4. This desired higher degree of flexibility can be obtained by applying a thread or cable of a more flexible material and/or structure imparting a more flexible thread or cable. The adapter may thus consist of, for example, a short cable section with a larger number of thin filaments than the guidewire itself, although with the same diameter as the guidewire. Such an embodiment is shown in Figure 1. The adapter is indicated with 8 in Figure 1 and is attached to one end with, for instance, a laser weld 9 and axially with its end surface against the capsule 3 or a connecting piece 6 placed on the capsule, whereby the longitudinal center lines essentially are lying in each other's extensions. The other end is attached in a similar manner, e.g., through a laser weld 10 with its head surface at the distal end of the guidewire.

According to a preferred embodiment of the invention, the greater flexibility of the distal end of the combination of guidewire and capsule is obtained through applying an adapter with smaller diameter than the guidewire itself and the capsule. A thread or cable with a smaller diameter automatically means a greater flexibility than a similar thread or cable with a greater diameter. This effect, of course, can be enhanced by applying a more supple material and/or a construction and/or combination imparting a more flexible thread or cable. Thus, for example the adapter can be built up from a larger number of and thinner filaments than the guidewire itself. Such an embodiment is shown in Figure 2. The adapter with reduced diameter is indicated with 20 and is connected with its head surface at one end, for instance through a laser weld 21, with a suitable connecting piece 22 that in turn is connected with the capsule 1. At the other end, the adapter 20 is attached, for instance, through a laser welding 23 with its head surface against the distal end of the guidewire. At both ends, the longitudinal center line of the adapter again essentially coincides with the centerline of the guidewire or the connecting piece, respectively, and the capsule. In the shown example, a short casing 24 is also applied, which is placed over the end of the adapter attached to the guidewire and welded to the guidewire. The inside diameter of the casing is such that the casing fits snugly around the adapter, whereas the

BEST AVAILABLE COPY

- 4 -

outside diameter of the casing is essentially equal to the diameter of the guidewire 2.

Applying such a casing prevents, even after a great number of bendings, that the outermost filaments of the adapter come loose from the weld and jut out. In a practical embodiment, the guidewire may consist of, for instance, a 0.9 mm diameter cable constructed of 1 x 19 filaments, whereas the more flexible adapter may consist of a 0.72 mm diameter cable constructed of 7 x 7 filaments. The casing may thus have a length of, for instance, ± 2 mm. In a practical embodiment, the adapter may have a length of, for instance, 10 - 15 cm, while the total length of the combination may be about 2 m.

It should be noted that according to the abovementioned, various modifications may be obvious to a person skilled in the art. This naturally applies to the dimensions that are solely provided as examples and, furthermore, for the structure of the cables and the choice of materials. Such modifications are deemed to be within the scope of the invention.

BEST AVAILABLE COPY

- 5 -

CLAIMS

1. A combination of a capsule for incorporating a radioactive source to be applied in brachytherapy and a guidewire, characterized in that the capsule is attached to
5 the guidewire through an adapter, in which the adapter comprises a cable or a thread with a flexibility greater than that of the guidewire.
2. A combination according to Claim 1, characterized in that the adapter has a smaller diameter than the
10 guidewire.
3. A combination according to Claims 1 or 2, characterized in that the adapter and the guidewire are welded with their front edges to one another, in which the
15 respective longitudinal center lines substantially coincide.
4. A combination according to claims 2 or 3, characterized in that a casing around the adapter is placed at the end of the adapter connected to the guidewire, which casing with its head surface is welded to the guidewire.
- 20 5. A combination according to claim 4, characterized in that the casing and the guidewire have substantially the same outside diameter.

BEST AVAILABLE COPY

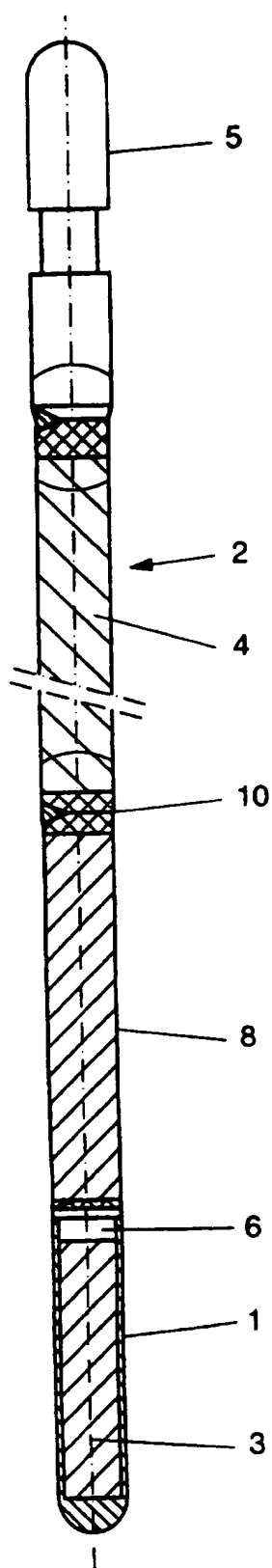


FIG. 1

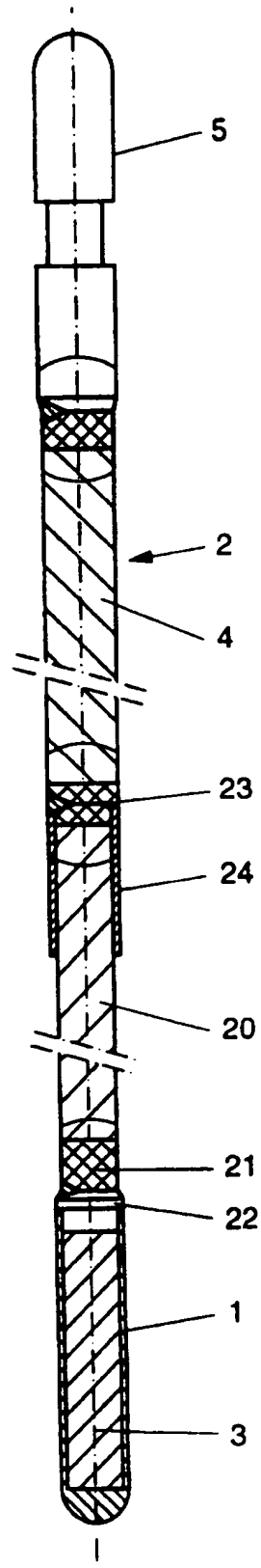


FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/NL 97/00385

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61N5/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 466 681 A (ÖSTERREICHISCHES FORSCHUNSZENTRUM SEIBERSDORF) 15 January 1992 see page 3, line 23 - line 50 ---	1
A	WO 92 00776 A (MALLINCKRODT) 23 January 1992 see page 10, line 1 - page 11, line 5 ---	1
A	WO 94 23789 A (MALLINCKRODT) 27 October 1994 see page 6, line 5 - line 12 ---	1
A	US 4 861 520 A (VAN'HOOF) 29 August 1989 cited in the application see claim 1 -----	1

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

9 September 1997

Date of mailing of the international search report

18.09.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+ 31-70) 340-3016

Authorized officer

Taccoen, J-F

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. J Application No

PCT/NL 97/00385

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0466681 A	15-01-92	AT 397468 B AT 147190 A AT 129911 T DE 59106840 D	25-04-94 15-09-93 15-11-95 14-12-95
WO 9200776 A	23-01-92	AT 138585 T AU 8407291 A CA 2087007 A DE 69119907 D DE 69119907 T EP 0541699 A ES 2087301 T JP 5509019 T	15-06-96 04-02-92 14-01-92 04-07-96 02-10-96 19-05-93 16-07-96 16-12-93
WO 9423789 A	27-10-94	AU 6706294 A CA 2160460 A EP 0695204 A HU 72942 A JP 8509143 T	08-11-94 27-10-94 07-02-96 28-06-96 01-10-96
US 4861520 A	29-08-89	EP 0367340 A	09-05-90